

Sheet 1 of 6SUBSTITUTE FORM PTO-1449  
(MODIFIED)U.S. DEPARTMENT OF COMMERCE  
PATENT AND TRADEMARK OFFICE

Attorney Docket No.

06727/008002

Serial No.

10/030,351

Applicant

Stace Lindsay et al.

Filing Date

January 7, 2002

Group

Not yet assigned

IDS Filed

May 1, 2002

Customer Number

21559

INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT  
(Use several sheets if necessary)

(37 C.F.R. §1.98(b))

## U.S. PATENTS

Examiner's Initials	Patent Number	Issue Date	Patentee	Class	Subclass	Filing Date (If Appropriate)
VB	4,692,332	09/08/87	John McMichael	424	88	01/18/85
VB	4,873,316	10/10/89	Harry Meade et al.	800	7	06/23/87
VB	4,877,610	10/31/89	John McMichael	424	88	08/18/87
VB	4,966,753	10/30/90	John McMichael	424	88	06/16/89
VB	4,970,071	11/13/90	John McMichael	424	88	09/26/89
VB	5,130,415	07/14/92	Mario Tecce et al.	530	324	07/24/89
VB	5,206,153	04/27/93	Taiki Tamaoki et al.	435	69.7	03/16/92
VB	5,302,698	04/12/94	Tomonori Morinaga et al.	530	350	04/27/90
VB	5,322,775	06/21/94	Anthony Clark et al.	435	69.1	11/22/91
VB	5,384,250	01/24/95	Robert A. Murgita	435	69.6	10/08/93
VB	5,589,604	12/31/96	William Drohan et al.	800	7	05/23/94
VB	5,633,076	05/27/97	Herman DeBoer et al.	800	25	11/16/93
VB	5,639,940	06/17/97	Ian Garner et al.	800	7	03/03/94

## FOREIGN PATENT OR PUBLISHED FOREIGN PATENT APPLICATION

Examiner's Initials	Document Number	Publication Date	Country or Patent Office	Class	Subclass	Translation (Yes/No)
VB	WO 86/04241	07/31/86	PCT			
VB	JP 2005866	01/10/90	Japan (Abstract)			Yes
VB	WO 94/10199	05/11/94	PCT			
VB	EP 0 487 229	09/24/97	Europe			
VB	WO 96/22787	08/01/96	PCT			
VB	WO 01/15709	03/08/01	PCT			

EXAMINER

DATE CONSIDERED

EXAMINER: Initial citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with the next communication to applicant.

Sheet 2 of 6

SUBSTITUTE FORM PTO-1449 (MODIFIED)	U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE	Attorney Docket No.	06727/008002
		Serial No.	10/030,351
		Applicant	Stace Lindsay et al.
		Filing Date	January 7, 2002
		Group	Not yet assigned
		IDS Filed	May 1, 2002
(37 C.F.R. §1.98(b))		Customer Number	21559

INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT  
(Use several sheets if necessary)

## U.S. PATENTS

VB	5,648,243	07/15/87	David Hurwitz et al.	435	69.6	09/21/94
	5,827,690	10/27/98	Harry Meade et al.	800	7	12/20/93
	5,843,705	12/01/98	Paul Ditullio et al.	800	7	02/21/95
	5,965,528	10/12/99	Robert A. Murgita	514	12	01/24/95
	6,288,034	09/11/01	Robert A. Murgita	514	12	11/05/98
VB	6,331,611	12/18/01	Robert A. Murgita	530	350	07/21/95


## OTHER DOCUMENTS (INCLUDING AUTHOR, TITLE, DATE, PLACE OF PUBLICATION)

VB	Abramsky et al., "Alpha-Fetoprotein Suppresses Experimental Allergic Encephalomyelitis," <i>Journal of Neuroimmunology</i> 2:1-7 (1982).
	Abramsky et al., "A Role of Alpha-Fetoprotein in Autoimmune Diseases," <i>Annals New York Academy of Sciences</i> 417:108-116 (1983).
	Aoyagi et al., "Differential Reactivity of Alpha-Fetoprotein with Lectins and Evaluation of its Usefulness in the Diagnosis of Hepatocellular Carcinoma," <i>Gann</i> 75:809-815 (1984).
	Biddle et al., "Specific Cytoplasmic Alpha-Fetoprotein Binding Protein in MCF-7 Human Breast Cancer Cells and Primary Breast Cancer Tissue," <i>Breast Cancer Research and Treatment</i> 10:279-286 (1987).
	Boismenu et al., "Expression of Domains of Mouse Alpha-Fetoprotein in Escherichia Coli," <i>Life Sciences</i> 43:673-681 (1988).
	Brenner et al., "Inhibitory Effect of Alpha-Fetoprotein on the Binding of Myasthenia Gravis Antibody to Acetylcholine Receptor," <i>Proc. Natl. Acad. Sci. USA</i> 77:3635-3639 (1980).
	Brenner et al., "Immunosuppression of Experimental Autoimmune Myasthenia Gravis by Alpha-Fetoprotein Rich Formation," <i>Immunology Letters</i> 3:163-167 (1981).
	Brenner et al., "Influence of Alpha-Fetoprotein on the <i>in Vitro</i> and <i>in Vivo</i> Immune Response to Acetylcholine Receptor," <i>Annals New York Academy of Sciences</i> 377:208-221 (1981).
VB	Buamah et al., "Serum Alpha-Fetoprotein Heterogeneity as a Means of Differentiating Between Primary Hepatocellular Carcinoma and Hepatic Secondaries," <i>Clinica. Chimica. Acta.</i> 139:313-316 (1984).

EXAMINER

DATE CONSIDERED

EXAMINER: Initial citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with the next communication to applicant.

SUBSTITUTE FORM PTO-1449 (MODIFIED)	U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE	Attorney Docket	06727/008002
		Serial No.	10/030,351
		Applicant	Stace Lindsay et al.
		Filing Date	January 7, 2002
		Group	Not yet assigned
		IDS Filed	May 1, 2002
		Customer Number	21559

## OTHER DOCUMENTS (INCLUDING AUTHOR, TITLE, DATE, PLACE OF PUBLICATION)

VB	Buschman et al., "Experimental Myasthenia Gravis Induced in Mice by Passive Transfer of Human Myasthenic Immunoglobulin," <i>Journal of Neuroimmunology</i> 13:315-330 (1987).
	Caturla et al., "The Thyroid Hormone Down-Regulates the Mouse Alpha-Fetoprotein Promoter," <i>Molec. and Cell. Endocrin.</i> 135:139-145 (1997).
	Cohen et al., "Suppression by Alpha-Fetoprotein of Murine Natural Killer Cell Activity Stimulated <i>in Vitro</i> and <i>in Vivo</i> by Interferon and Interleukin 2," <i>Scand. J. Immunol.</i> 23:211-223 (1986).
	Dattwyler et al., "Binding of Alpha-Fetoprotein to Murine T Cells," <i>Nature</i> 256:656-657 (1975).
	Galarneau et al., "The Alpha <sub>1</sub> -Fetoprotein Locus is Activated by a Nuclear Receptor of the <i>Drosophila</i> FTZ-F1 Family," <i>Molec. and Cell. Biol.</i> 16:3853-3865 (1996).
	Gershwin et al., "The Influence of Alpha-Fetoprotein on Moloney Sarcoma Virus Oncogenesis: Evidence for Generation of Antigen Nonspecific Suppressor T Cells," <i>The Journal of Immunology</i> 121:2292-2297 (1978).
	Gibbs et al., "Structure, Polymorphism, and Novel Repeated DNA Elements Revealed by a Complete Sequence of the Human Alpha-Fetoprotein Gene," <i>Biochemistry</i> 26:1332-1343, 1987.
	Giuliani et al., "Synthesis and Characterization of a Recombinant Fragment of Human Alpha-Fetoprotein with Antigenic Selectivity Versus Albumin," <i>Protein Engineering</i> 2:605-610 (1989).
	Glazier et al., "Graft-Versus-Host Disease in Cyclosporin A-Treated Rats After Syngeneic and Autologous Bone Marrow Reconstitution," <i>J. Exp. Med.</i> 158:1-8 (1983).
	Goidl et al., "Studies on the Mechanisms of Alpha-Fetoprotein Induction of Immune Suppressive Activity," <i>from Developmental Immunobiology, Proceedings of the Fifth Irwin Strasburger Memorial Seminar on Immunology</i> eds. Siskind et al., 35-55 (1979).
	Hamel et al., "Phenotype and Function of Bone Marrow-Derived T- and Non-T-Cells Activated <i>in Vitro</i> by Alpha-Fetoprotein," <i>Biological Activities of Alpha<sub>1</sub>-Fetoprotein</i> 1:167-177 (1987).
	Heyward et al., "Early Detection of Primary Hepatocellular Carcinoma by Screening for Alpha-Fetoprotein in High-Risk Families," <i>The Lancet</i> 2:1161-1162 (1983).
	Hooper et al., "Regulation of Murine T-Cell Responses to Autologous Antigens by Alpha-Fetoprotein," <i>Cellular Immunology</i> 63:417-425 (1981).
	Hooper et al., "Suppression of Primary and Secondary Autologous Mixed Lymphocyte Reactions by Murine Alpha-fetoprotein," <i>Oncodevelopmental Biology and Medicine</i> 3:151-160 (1982).
	Hooper et al., "Selective Inhibition of Murine T-Cell Proliferation and Lymphokine-Activated Natural Killer Cell Function by Alpha-Fetoprotein," <i>Biological Activities of Alpha<sub>1</sub>-Fetoprotein</i> eds. Mizejewski et al. 1:153-165 (1987).
VB	Hooper et al., "Human AFP Inhibits Cell Proliferation and NK-Like Cytotoxic Activity Generated in Autologous, but not in Allogeneic Mixed Lymphocyte Reactions," <i>Biological Activities of Alpha<sub>1</sub>-Fetoprotein</i> 2:183-197 (1989).
EXAMINER	DATE CONSIDERED 02/16/05

EXAMINER: Initial citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with the next communication to applicant.

SUBSTITUTE FORM PTO-1449

U.S. DEPARTMENT OF COMMERCE  
PATENT AND TRADEMARK OFFICE

Attorney Docket

06727/008002

Serial No.

10/030,351

Applicant

Stace Lindsay et al.

Filing Date

January 7, 2002

Group

Not yet assigned

IDS Filed

May 1, 2002

Customer Number

21559

INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT  
(Use several sheets if necessary)

(37 C.F.R. §1.98(b))

## OTHER DOCUMENTS (INCLUDING AUTHOR, TITLE, DATE, PLACE OF PUBLICATION)

13	Hoskin et al., "In Vitro Activation of Bone Marrow-Derived T-and Non-T-Cell Subsets by Alpha-Fetoprotein," <i>Cellular Immunology</i> 96:163-174 (1985).
	Hoskin et al., "Analysis of Pregnancy-Associated Immunoregulatory Pathways," <i>Alpha-Fetoprotein and Congenital Disorders</i> 59-78 (1985).
	Hoskin et al., "Specific Maternal Anti-Fetal Lymphoproliferative Responses and Their Regulation by Natural Immunosuppressive Factors," <i>Clin. Exp. Immunol.</i> 76:262-267 (1989).
	Innis et al., "Amplification of Alpha-Fetoprotein Complementary DNA by Insertion into a Bacterial Plasmid," <i>Archives of Biochemistry and Biophysics</i> 195:128-135 (1979).
	Ishiguro et al., "Serum Alpha-Fetoprotein Subfractions in Patients with Primary Hepatoma or Hepatic Metastasis of Gastric Cancer," <i>Cancer</i> 55:156-159 (1985).
✓	Jacobson et al., "Inhibition of Estrogen-Dependent Breast Cancer Growth by a Reaction Product of Alpha-Fetoprotein and Estradiol," <i>Cancer Research</i> 50:415-420 (1990).
	Jiang et al., "Role of CD8+ T Cells in Murine Experimental Allergic Encephalomyelitis," <i>Science</i> 256:1213-1215 (1992).
✓	Keller et al., "Immunosuppressive Properties of AFP: Role of Estrogens," from <i>Onco-Developmental Gene Expression</i> eds. Fishman et al. 287-295 (1976).
13	Kerr et al., "The Bladder as a Bioreactor: Urothelium Production and Secretion of Growth Hormone into Urine," <i>Nat. Biotechnol.</i> 16:75-79, 1998.
✓	Kikutani et al., "The Murine Autoimmune Diabetes Model: NOD and Related Strains," <i>Advances in Immunology</i> 51:285-322 (1992).
✓	Line et al., "Medical Potential of AFP as a Tumor Imaging Agent," <i>Biological Activities of Alpha-Fetoprotein</i> 2:139-148 (1989).
	Lu et al., "Alpha-Fetoprotein Inhibits Macrophage Expression of Ia Antigens," <i>The Journal of Immunology</i> 132:1722-1727 (1984).
	Masuda et al., "Selective Antitumor Effect of Thioether-Linked Immunotoxins Composed of Gelonin and Monoclonal Antibody to Alpha-Fetoprotein or its F(ab') <sub>2</sub> Fragment," <i>Tumor Biol.</i> 15:175-183 (1994).
	Mizejewski, "Alpha-Fetoprotein Testing: Regulatory and Technical Considerations," <i>Laboratory Management</i> (1987).
13	Morinaga et al., "Primary Structures of Human Alpha-Fetoprotein and its mRNA," <i>Proc. Natl. Acad. Sci. USA</i> 80:4604-4608 (1983).
	Moro et al., "Monoclonal Antibodies Directed Against a Widespread Oncofetal Antigen: The Alpha-Fetoprotein Receptor," <i>Tumor Biol.</i> 14:116-130 (1993).
13	Murgita et al., "Suppression of the Immune Response by Alpha-Fetoprotein I. The Effect of Mouse Alpha-Fetoprotein on the Primary and Secondary Antibody Response," <i>The Journal of Experimental Medicine</i> 141:269-289 (1975).

EXAMINER

DATE CONSIDERED

02/16/05

EXAMINER: Initial citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with the next communication to applicant.

SUBSTITUTE FORM PTO-1449  
(MODIFIED)U.S. DEPARTMENT OF COMMERCE  
PATENT AND TRADEMARK OFFICE

Attorney Docket No.

06727/008002

Serial No.

10/030,351

Applicant

Stace Lindsay et al.

Filing Date

January 7, 2002

Group

Not yet assigned

IDS Filed

May 1, 2002

Customer Number

21559


 INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT  
(Use several sheets if necessary)

(37 C.F.R. §1.98(b))

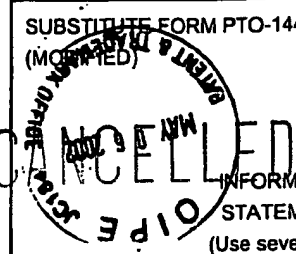

## OTHER DOCUMENTS (INCLUDING AUTHOR, TITLE, DATE, PLACE OF PUBLICATION)

VB	Murgita et al., "Suppression of the Immune Response by Alpha-Fetoprotein II. The Effect of Mouse Alpha-Fetoprotein on Mixed Lymphocyte Reactivity and Mitogen-Induced Lymphocyte Transformation," <i>The Journal of Experimental Medicine</i> 141:440-452 (1975).
	Murgita, "The Immunosuppressive Role of Alpha-Fetoprotein During Pregnancy," <i>Scand. J. Immunol.</i> 5:1003-1014 (1976).
	Murgita et al., "The Effects of Mouse Alpha-Fetoprotein on T-Cell-Dependent and T-Cell-Independent Immune Responses <i>in Vitro</i> ," <i>Scand. J. Immunol.</i> 5:1215-1220 (1976).
	Murgita et al., "Alpha-Fetoprotein Induces Suppressor T Cells <i>in Vitro</i> ," <i>Nature</i> 267:257-259 (1977).
	Murgita et al., "Adult Murine T Cells Activated <i>in Vitro</i> by Alpha-Fetoprotein and Naturally Occurring T Cells in Newborn Mice: Identity in Function and Cell Surface Differentiation Antigens," <i>Proc. Natl. Acad. Sci. USA</i> 75:2897-2901 (1978).
	Murgita et al., "Effects of Human Alpha-Fetoprotein on Human B and T Lymphocyte Proliferation <i>in Vitro</i> ," <i>Clin. Exp. Immunol.</i> 33:347-356 (1978).
	Murgita et al., "Selective Immunoregulatory Properties of Alpha-Fetoprotein," <i>La Ricerca Clin. Lab.</i> 9:327-342 (1979).
	Murgita et al., "Characterization of Murine Newborn Inhibitory T Lymphocytes: Functional and Phenotypic Comparison with an Adult T Cell Subset Activated <i>in Vitro</i> by Alpha-Fetoprotein," <i>Eur. J. Immunol.</i> 11:957-964 (1981).
	Murgita et al., "Regulation of Immune Functions in the Fetus and Newborn," <i>Prog. Allergy</i> 29:54-133 (1981).
	Nelson et al., "Maternal-Fetal Disparity in HLA Class II Alloantigens and the Pregnancy-Induced Amelioration of Rheumatoid Arthritis," <i>The New England Journal of Medicine</i> 329:466-471 (1993).
	Nishi et al., "Expression of Rat Alpha-Fetoprotein cDNA in <i>Escherichia coli</i> and in Yeast," <i>J. Biochem.</i> 104:968-972 (1988).
	O'Neill et al., "Regulation of Human Lymphocyte Activation by Alpha-Fetoprotein: Evidence for Selective Suppression of Ia-Associated T-Cell Proliferation <i>in vitro</i> ," <i>Oncodevelopmental Biology and Medicine</i> 3:135-150 (1982).
	Peck et al., "Cellular and Genetic Restrictions in the Immunoregulatory Activity of Alpha-Fetoprotein I. Selective Inhibition of Anti-Ia-Associated Proliferative Reactions," <i>J. Exp. Med.</i> 147:667-683 (1978).
VB	Peck et al., "Cellular and Genetic Restrictions in the Immunoregulatory Activity of Alpha-Fetoprotein II. Alpha-Fetoprotein-Induced Suppression of Cytotoxic T Lymphocyte Development," <i>J. Exp. Med.</i> 148:360-372 (1978).

EXAMINER

DATE CONSIDERED

EXAMINER: Initial citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with the next communication to applicant.

SUBSTITUTE FORM PTO-1449 U.S. DEPARTMENT OF COMMERCE (MODIFIED) PATENT AND TRADEMARK OFFICE  INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use several sheets if necessary) (37 C.F.R. §1.98(b))		Attorney Docket No. 06727/008002 Serial No. 10/030,351 Applicant Stace Lindsay et al. Filing Date January 7, 2002 Group Not yet assigned IDS Filed May 1, 2002 Customer Number 21559
OTHER DOCUMENTS (INCLUDING AUTHOR, TITLE, DATE, PLACE OF PUBLICATION)		
13	Peck et al., "Cellular and Genetic Restrictions in the Immunoregulatory Activity of Alpha-Fetoprotein III. Role of the MLC-Stimulating Cell Population in Alpha-Fetoprotein-Induced Suppression of T Cell-Mediated Cytotoxicity," <i>J. of Immunology</i> 128:1134-1140 (1982).	
	Sambrook et al., "Expression of Cloned Genes in <i>Escherichia coli</i> ," <i>Molecular Cloning</i> 17:37-43 (1989).	
	Sell, "Alphafetoprotein," <i>Cancer Markers Diagnostic and Developmental Significance</i> 249-293 (1980).	
x	Semeniuk et al., "Immunoregulation by Recombinant Alpha-Fetoproteins Produced in Eukaryotic and Prokaryotic Expression Systems," Abstract 2799, <i>Experimental Biology</i> 94 <sup>TM</sup> (1994).	
✓	Soto et al., "Control of Growth of Estrogen-Sensitive Cells: Role for Alpha-Fetoprotein," <i>Proc. Natl. Acad. Sci. USA</i> 77:2084-2087 (1980).	
	van Oers, et al., "Isolation and Characterization of a Distinct Immunoregulatory Isoform of Alpha-Fetoprotein Produced by the Normal Fetus," <i>J. Exp. Med.</i> 170:811-825 (1989).	
	van Oers et al., "Analytical- and Preparative-Scale Separation of Molecular Variants of Alpha-Fetoprotein by Anion-Exchange Chromatography on Monobead <sup>TM</sup> Resins," <i>Journal of Chromatography</i> 525:59-69 (1990).	
	Villacampa et al., "Alpha-Fetoprotein Receptors in a Human Breast Cancer Cell Line," <i>Biochemical and Biophysical Research Communications</i> 122:1322-1327 (1984).	
13	Yamamoto et al., "Expression of Human Alpha-Fetoprotein in Yeast," <i>Life Sciences</i> 46:1679-1686 (1990).	
EXAMINER		
	DATE CONSIDERED 02/16/05	
EXAMINER: Initial citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with the next communication to applicant.		